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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/310,667	05/12/99	ECKER	D IBIS-0012

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EXAMINER

LU, F

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/310,667

Applicant(s)

ECKER ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2000 and 29 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29 and 35-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 35-41, and 43-51 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on August 9, 2000 has been entered as Paper No: 10. The claims pending in this application are claims 26-29 and 35-50. Rejection and or objection not reiterated from the previous office action are hereby withdrawn. The following rejections are based on amendment and new IDS filed on November 27, 2000.

Drawings

2. Applicant's request that "formal drawings correcting the deficiencies noted in Form PTO 948 will be filed upon an indication of allowable subject matter" has been granted by the examiner.

Sequence Rules Compliance

3. The sequencing listing submitted on December 29, 2000 application has complied with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures and has been entered by the office.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 26 and 35-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Note that claims 36-50 are dependent on claim 35.

Note the specification does not adequately describe that said oligonucleotide does not comprise the iron element which the claims are directed to. It is well established that there is nothing inherently ambiguous or uncertain about a negative limitation. However, it is also well established [see *Ex parte Graciously* 231 USPO 393 (Bd App. 1983)] that any negative limitations or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for exclusion. Furthermore, MPEP 2163.06 states that "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." In view of the embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of products encompass in the claims at the time of the application was filled. Therefore, the written description requirement has not been satisfied.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V.*

Mahurkar 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description"

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requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 36-50 are dependent on claim 35.

Claims 35 and 39-42 recite the limitation "said target nucleic acid" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. § 102/103

8 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 26 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams *et al.*, (Nucleic Acids Res. 22, 4660-4666, 1994).

Williams *et al.*, teach changes in the stem-loop at the 3' terminus of histone mRNA affects its nucleocytoplasmic transport and cytoplasmic regulation. They showed that a protein, the stem-loop binding protein (SLBP), could bind the 3' end of histone mRNA and proper stem-loop RNA-SLBP interactions were required for efficient nuclear-cytoplasmic transport and proper regulation of histone mRNA degradation (see abstract and right column in page 4460).

Williams *et al.*, teach all the limitation recited by claims 26 and 35.

11. Claims 27-29 and 35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garcia *et al.*, (J. Mol. Biol. 254, 247-259, 1995).

Garcia *et al.*, teach solution structure of the ribosome-binding domain of *E. coli* translation initiation factor IF3. As acknowledged by Garcia, in prokaryotic organisms, the first

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step in the initiation of protein translation was the binding of the 3' region of the 16S ribosomal RNA to the complementary 'Shine & Dalgarno' sequence located a few bases upstream to the start codon of mRNA. This ensured a pre-positioning of the 30S ribosome (see page 247). Note that, although Garcia *et al.*, did not directly show to this interaction was specific for prokaryotic organisms as described claims 27 and 35, in the absence of convincing evidence to the contrary the claimed invention, this limitation is considered as inherent to the reference taught by Garcia *et al.*, since it has been well know that eucaryotes do not utilize this mRNA-rRNA base pair mechanism and 'Shine & Dalgarno' sequence has been only found in prokaryotic organisms (see Protein Synthesis in any Biochemistry Text Book). Note it has been well know that the interaction between IF3 and 30S subunit of the ribosome is specific for prokaryotic organisms (see right column in page 248 and Protein Synthesis in any Biochemistry Text Book).

12. Claims 35-41 and 43-50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ray Gutell (Nucleic Acids Res. 21, 3051-3054, 1993).

Ray Gutell teaches collection of small subunit (16S- and 16S-like) ribosomal RNA structure. In this study, they aligned 16S- and 16S-like ribosomal RNA sequence from different prokaryotic and eukaryotic organisms such as *E. coli* and *C. elegans* in 16S database and compared their second structure of (see left column in page 3054, Figure 1 in page 3052 and Figure 3 in page 3054). Note that, although Ray Gutell did not directly show a molecular interaction site in 16S- and 16S-like ribosomal RNA and to determine secondary structure of

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conserved region of 16S- and 16S-like ribosomal RNA described in claim 35, in the absence of convincing evidence to the contrary the claimed invention, these limitation are considered as inherent to the reference taught by Ray Gutell since: (1) it has been well know that 16S- and 16S-like ribosomal RNA could interact with mRNA and modulated protein translation (see Protein Synthesis in any Biochemistry Text Book) and (2) predicted secondary structure of 16S- and 16S-like ribosomal RNA as shown in Figures 1-3 contains some conserved regions. Descriptor described in claims 37, 38, and 49 could be considered as RNA sequence.

Conclusion

13. Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(1) De Rijk *et al.*, Database on the structure of large ribosomal subunit RNA. Nucleic Acids Res. 22, 3495-3501, 1994.

(2) Zehner et al., RNA-protein interactions within the 3' untranslated region of vimentin mRNA. Nucleic Acids Res. 25, 3362-3370, 1997.

15. No claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
April 23, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

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